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I

106TH CONGRESS
1ST SESSION

H. R. 1109

To amend title XVIII of the Social Security Act to provide for coverage of outpatient prescription drugs under part B of the Medicare Program, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 15, 1999

Mr. ENGEL (for himself, Mr. NADLER, Mr. OWENS, Mr. CROWLEY, Mr. RUSH, Mr. ACKERMAN, Mr. WYNN, Mr. WEINER, and Mrs. MCCARTHY of New York) introduced the following bill; which was referred to the Committee on Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend title XVIII of the Social Security Act to provide for coverage of outpatient prescription drugs under part B of the Medicare Program, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the "Medicare Outpatient
5 Prescription Drug Coverage Act of 1999".

1 **SEC. 2. MEDICARE COVERAGE OF OUTPATIENT PRESCRIP-**
2 **TION DRUGS.**

3 (a) DESCRIPTION OF COVERED OUTPATIENT
4 DRUGS.—

5 (1) COVERAGE.—Section 1861(s)(2)(J) of the
6 Social Security Act (42 U.S.C. 1395x(s)(2)(J)) is
7 amended to read as follows:

8 “(J) covered outpatient drugs;”.

9 (2) DRUGS DESCRIBED.—Section 1861(t) of
10 such Act (42 U.S.C. 1395x(t)) is amended—

11 (A) in the heading, by adding at the end
12 the following: “; Covered Outpatient Drugs”;

13 (B) in paragraph (1)—

14 (i) by striking “paragraph (2)” and
15 inserting “the succeeding paragraphs of
16 this subsection”, and

17 (ii) by striking the period at the end
18 and inserting “, but only if used for a
19 medically accepted indication (as described
20 in paragraph (4)).”; and

21 (C) by striking paragraph (2) and inserting the
22 following:

23 “(2) Subject to paragraph (3), the term ‘covered out-
24 patient drug’ means—

25 “(A) a drug which may be dispensed only upon
26 prescription and—

1 “(i) which is approved for safety and effec-
2 tiveness as a prescription drug under section
3 505 or 507 of the Federal Food, Drug, and
4 Cosmetic Act or which is approved under sec-
5 tion 505(j) of such Act;

6 “(ii)(I) which was commercially used or
7 sold in the United States before the date of the
8 enactment of the Drug Amendments of 1962 or
9 which is identical, similar, or related (within the
10 meaning of section 310.6(b)(1) of title 21 of the
11 Code of Federal Regulations) to such a drug,
12 and (II) which has not been the subject of a
13 final determination by the Secretary that it is
14 a ‘new drug’ (within the meaning of section
15 201(p) of the Federal Food, Drug, and Cos-
16 metic Act) or an action brought by the Sec-
17 retary under section 301, 302(a), or 304(a) of
18 such Act to enforce section 502(f) or 505(a) of
19 such Act; or

20 “(iii)(I) which is described in section
21 107(c)(3) of the Drug Amendments of 1962
22 and for which the Secretary has determined
23 there is a compelling justification for its med-
24 ical need, or is identical, similar, or related
25 (within the meaning of section 310.6(b)(1) of

1 title 21 of the Code of Federal Regulations) to
2 such a drug, and (II) for which the Secretary
3 has not issued a notice of an opportunity for a
4 hearing under section 505(e) of the Federal
5 Food, Drug, and Cosmetic Act on a proposed
6 order of the Secretary to withdraw approval of
7 an application for such drug under such section
8 because the Secretary has determined that the
9 drug is less than effective for all conditions of
10 use prescribed, recommended, or suggested in
11 its labeling;

12 “(B) a biological product which—

13 “(i) may only be dispensed upon prescrip-
14 tion,

15 “(ii) is licensed under section 351 of the
16 Public Health Service Act, and

17 “(iii) is produced at an establishment li-
18 censed under such section to produce such
19 product; and

20 “(C) insulin certified under section 506 of the
21 Federal Food, Drug, and Cosmetic Act.

22 “(3) The term ‘covered outpatient drug’ does not
23 include—

24 “(A) any drug, biological product, or insulin
25 when furnished as part of, or as incident to, a diag-

1 nostic service or any other item or service for which
 2 payment may be made under this title (other than
 3 physicians' services or services which would be physi-
 4 cians' services if furnished by a physician); or

5 “(B) any drug that is intravenously adminis-
 6 tered in a home setting.

7 “(4) For purposes of paragraph (2), the term ‘medi-
 8 cally accepted indication’, with respect to the use of an
 9 outpatient drug, includes—

10 “(A) any use which has been approved by the
 11 Food and Drug Administration for the drug, and

12 “(B) any other use of the drug, unless the Sec-
 13 retary determines that such use is not medically ap-
 14 propriate.”.

15 (3) CONFORMING AMENDMENTS REPEALING
 16 SEPARATE COVERAGE OF CERTAIN DRUGS AND
 17 PRODUCTS.—(A) Effective January 1, 2001, section
 18 1861(s)(2) of such Act (42 U.S.C. 1395x(s)(2)) is
 19 amended—

20 (i) in each of subparagraphs (A) and (B),
 21 by striking “(including drugs” and all that fol-
 22 lows through “self-administered)”;

23 (ii) by striking subparagraphs (G), (I),
 24 (O), (Q), and (T);

1 (iii) by adding “and” at the end of sub-
2 paragraph (R); and

3 (iv) by striking “; and” at the end of sub-
4 paragraph (S) and inserting a period.

5 (B) Effective January 1, 2001, section 1861 of
6 such Act (42 U.S.C. 1395x) is amended by striking
7 the subsection (kk).

8 (C) Effective January 1, 2001, section 1881(b)
9 of such Act (42 U.S.C. 1395rr(b)) is amended—

10 (i) in the first sentence of paragraph (1)—

11 (I) by striking “, (B)” and inserting
12 “, and (B)”;

13 (II) by striking “, and (C)” and all
14 that follows and inserting a period; and

15 (ii) in paragraph (11)—

16 (I) by striking “(11)(A)” and insert-
17 ing “(11)”;

18 (II) by striking subparagraphs (B)
19 and (C).

20 (b) DEDUCTIBLE AND PAYMENT AMOUNTS.—(1)
21 Section 1833(a)(1) of such Act (42 U.S.C. 1395l(a)(1)),
22 as amended by section 2(c)(1), is amended—

23 (A) by striking “and (S)” and inserting “(S)”;

24 and

1 (B) by striking the semicolon at the end and in-
2 serting the following “, and (T) with respect to ex-
3 penses incurred for covered outpatient drugs, the
4 amounts paid shall be the amounts determined
5 under section 1834(e)(2);”.

6 (2) Section 1833(a)(2) of such Act (42 U.S.C.
7 1395l(a)(2)) is amended by inserting “(other than covered
8 outpatient drugs)” after “(2) in the case of services”.

9 (3) Section 1833(b) of such Act (42 U.S.C. 1395l(b))
10 is amended—

11 (A) in clause (1), by inserting “or for covered
12 outpatient drugs” after “1861(s)(10)(A)”, and

13 (B) in clause (2), by inserting “or with respect
14 to covered outpatient drugs” after “1861(kk))”.

15 (4) Section 1834 of such Act (42 U.S.C. 1395m) is
16 amended by inserting after subsection (d) the following
17 new subsection:

18 “(e) PAYMENT FOR COVERED OUTPATIENT
19 DRUGS.—

20 “(1) DEDUCTIBLE.—

21 “(A) APPLICATION.—

22 “(i) IN GENERAL.—Except as pro-
23 vided in clauses (ii) and (iii), payment
24 shall be made under paragraph (2) only
25 with respect to expenses incurred by an in-

1 dividual for covered outpatient drugs dur-
2 ing a calendar year on or after such date
3 in the year as the Secretary determines
4 that the individual has incurred expenses
5 in the year for covered outpatient drugs
6 (during a period in which the individual is
7 entitled to benefits under this part) equal
8 to the amount of the prescription drug de-
9 ductible specified in subparagraph (C) for
10 that year.

11 “(ii) DEDUCTIBLE NOT APPLIED TO
12 1ST YEAR IMMUNOSUPPRESSIVES.—The
13 prescription drug deductible established
14 under this paragraph shall not apply to
15 drugs described in section 1861(t)(2)(A)
16 used in immunosuppressive therapy and
17 furnished, to an individual who receives an
18 organ transplant for which payment is
19 made under this title, within 1 year after
20 the date of the transplant.

21 “(B) RESPONSE TO APPLICATION.—If the
22 system described in section 1842(u)(4) has not
23 been established and an individual applies to
24 the Secretary to establish that the individual
25 has met the requirement of subparagraph (A),

1 the Secretary shall promptly notify the indi-
2 vidual (and, if the application was submitted by
3 or through a participating pharmacy, the phar-
4 macy) as to the date (if any) as of which the
5 individual has met such requirement.

6 “(C) PRESCRIPTION DRUG DEDUCTIBLE
7 AMOUNT.—The prescription drug deductible
8 specified in this subparagraph for—

9 “(i) 2001 is \$250, and

10 “(ii) any succeeding year, is the pre-
11 scription drug deductible for the preceding
12 year, increased by the percentage by which
13 the monthly premium under section 1839
14 for months during the year exceeds the
15 monthly premium under such section for
16 months during the preceding year.

17 “(2) PAYMENT AMOUNT.—

18 “(A) IN GENERAL.—Subject to the pre-
19 scription drug deductible established under
20 paragraph (1)(A) and except as provided in
21 subparagraph (B), the amounts payable under
22 this part with respect to a covered outpatient
23 drug is equal to 80 percent of the lesser of—

24 “(i) the actual charge for the drug, or

1 “(ii) the applicable payment limit es-
2 tablished under paragraph (3).

3 “(B) TREATMENT OF CERTAIN COST-
4 BASED PREPAID ORGANIZATIONS.—In applying
5 subparagraph (A) in the case of a
6 Medicare+Choice organization under part C, an
7 organization under a reasonable cost reimburse-
8 ment contract under section 1876, and in the
9 case of an organization receiving payment
10 under section 1833(a)(1)(A) and providing cov-
11 erage of covered outpatient drugs, the Secretary
12 shall provide for an appropriate adjustment in
13 the payment amounts otherwise made to reflect
14 the aggregate increase in payments that would
15 otherwise be made with respect to enrollees in
16 such an organization if payments were made
17 other than under such clause or such a contract
18 on an individual-by-individual basis.

19 “(3) PAYMENT LIMITS.—

20 “(A) PAYMENT LIMIT FOR NON-MULTIPLE
21 SOURCE DRUGS AND MULTIPLE-SOURCE DRUGS
22 WITH RESTRICTIVE PRESCRIPTIONS.—In the
23 case of a drug that either is not a multiple
24 source drug (as defined in paragraph (9)(A)) or
25 is a multiple source drug and has a restrictive

1 prescription (as defined in paragraph (9)(B)),
2 the payment limit for the drug under this para-
3 graph for a payment calculation period is equal
4 to the lesser of—

5 “(i) the 90th percentile of the actual
6 charges (computed on a statewide basis,
7 carrier-wide basis, or other appropriate ge-
8 ographic area basis, as specified by the
9 Secretary) for the drug for the second pre-
10 vious payment calculation period, adjusted
11 (as the Secretary determines to be appro-
12 priate) to reflect the number of tablets (or
13 other dosage units) dispensed; or

14 “(ii) the amount of the administrative
15 allowance (established under paragraph
16 (4)) plus the product of—

17 “(I) the number of tablets (or
18 other dosage units) dispensed, and

19 “(II) the per tablet or unit aver-
20 age wholesale price for such drug (as
21 determined under subparagraph (C)
22 for the period for purposes of this
23 subparagraph).

24 “(B) PAYMENT LIMIT FOR MULTIPLE
25 SOURCE DRUGS WITHOUT RESTRICTIVE PRE-

1 SCRIPTIONS.—In the case of a drug that is a
2 multiple source drug but does not have a re-
3 strictive prescription, the payment limit for the
4 drug under this paragraph for a payment cal-
5 culation period is equal to the amount of the
6 administrative allowance (established under
7 paragraph (4)) plus the product of—

8 “(i) the number of tablets (or other
9 dosage units) dispensed, and

10 “(ii) the unweighted median of the
11 per tablet or unit average wholesale prices
12 (determined under subparagraph (C) for
13 purposes of this subparagraph) for such
14 drug for the period.

15 “(C) DETERMINATION OF UNIT PRICE.—

16 “(i) IN GENERAL.—For purposes of
17 this paragraph, the Secretary shall deter-
18 mine, with respect to the dispensing of a
19 covered outpatient drug in a payment cal-
20 culation period (beginning on or after Jan-
21 uary 1, 2001), the per tablet or unit aver-
22 age wholesale price for the drug.

23 “(ii) BASIS FOR DETERMINATIONS.—

24 “(I) DETERMINATION FOR NON-
25 MULTIPLE-SOURCE DRUGS.—For pur-

poses of subparagraph (A), such determination shall be based on a biannual survey conducted by the Secretary of a representative sample of direct sellers, wholesalers, or pharmacies (as appropriate) of wholesale (or comparable direct) prices (excluding discounts to pharmacies); except that if, because of low volume of sales for the drug or other appropriate reasons or in the case of covered outpatient drugs during 2001, the Secretary determines that such a survey is not appropriate with respect to a specific drug, such determination shall be based on published average wholesale (or comparable direct) prices for the drug.

“(II) DETERMINATION FOR MULTIPLE-SOURCE DRUGS.—For purposes of subparagraph (B), the Secretary may base the determination under this subparagraph on the published average wholesale (or comparable direct) prices for the drug or on a bian-

1 nual survey conducted by the Sec-
2 retary of a representative sample of
3 direct sellers, wholesalers, or phar-
4 macists (as appropriate) of wholesale
5 (or comparable direct) prices (exclud-
6 ing discounts to pharmacies).

7 “(III) COMPLIANCE WITH SUR-
8 VEY REQUIRED.—If a wholesaler or
9 direct seller of a covered outpatient
10 drug refuses, after being requested by
11 the Secretary, to provide the informa-
12 tion required in a survey under this
13 clause, or deliberately provides infor-
14 mation that is false, the Secretary
15 may impose a civil money penalty of
16 not to exceed \$10,000 for each such
17 refusal or provision of false informa-
18 tion. The provisions of section 1128A
19 (other than subsections (a) and (b))
20 shall apply to civil money penalties
21 under the previous sentence in the
22 same manner as such provisions apply
23 to a penalty or proceeding under sec-
24 tion 1128A(a). Information gathered
25 pursuant to the survey shall not be

disclosed except as the Secretary determines to be necessary to carry out the purposes of this part.

“(iii) QUANTITY AND TIMING.—Such determination shall be based on the price or prices for purchases in reasonable quantities and shall be made for a payment calculation period based on prices for the first day of the first month of the previous payment calculation period.

“(iv) GEOGRAPHIC BASIS.—The Secretary shall make such determination, and calculate the payment limits under this paragraph, on a national basis.

“(v) ADJUSTMENT FOR GEOGRAPHIC VARIATIONS IN COSTS.—The Secretary shall adjust the payment limits under this paragraph to take account of limitations on the availability of drug products and variations among regions in the average wholesale prices for a drug product, using an appropriate index as determined by the Secretary.

“(4) ADMINISTRATIVE ALLOWANCE FOR PURPOSES OF PAYMENT LIMITS.—

1 “(A) IN GENERAL.—Except as provided in
2 subparagraph (B), for drugs dispensed in—

3 “(i) 2001, the administrative allow-
4 ance under this paragraph is—

5 “(I) \$5.00 for drugs dispensed by
6 a participating pharmacy, or

7 “(II) \$3.00 for drugs dispensed
8 by another pharmacy; or

9 “(ii) a subsequent year, the adminis-
10 trative allowance under this paragraph is
11 the administrative allowance under this
12 paragraph for the preceding year increased
13 by the percentage increase (if any) in the
14 implicit price deflator for gross national
15 product (as published by the Department
16 of Commerce in its ‘Survey of Current
17 Business’) over the 12-month period end-
18 ing with August of such preceding year.

19 Any allowance determined under the clause (ii)
20 which is not a multiple of 1 cent shall be round-
21 ed to the nearest multiple of 1 cent.

22 “(B) ADJUSTMENT IN ALLOWANCE FOR
23 MAIL SERVICE PHARMACIES.—The Secretary
24 may, by regulation and after consultation with
25 pharmacists, elderly groups, and private insur-

ers, reduce the administrative allowances established under subparagraph (A) for any drug dispensed by a mail service pharmacy (as defined by the Secretary) based on differences between such pharmacies and other pharmacies with respect to operating costs and other economies.

“(5) ASSURING APPROPRIATE PRESCRIBING AND DISPENSING PRACTICES.—

“(A) IN GENERAL.—The Secretary shall establish a program to identify (and to educate physicians and pharmacists concerning)—

“(i) instances or patterns of unnecessary or inappropriate prescribing or dispensing practices for covered outpatient drugs;

“(ii) instances or patterns of substandard care with respect to such drugs; and

“(iii) potential adverse reactions.

“(B) STANDARDS.—In carrying out the program under subparagraph (A), the Secretary shall establish for each covered outpatient drug standards for the prescribing of the drug which are based on accepted medical practice. In es-

1 tablishing such standards, the Secretary shall
2 incorporate standards from such current au-
3 thoritative compendia as the Secretary may se-
4 lect; except that the Secretary may modify such
5 a standard by regulation on the basis of sci-
6 entific and medical information that such
7 standard is not consistent with the safe and ef-
8 fective use of the drug.

9 “(C) PROHIBITION OF FORMULARY.—
10 Nothing in this title (other than section
11 1862(c)) shall be construed as authorizing the
12 Secretary to exclude from coverage or to deny
13 payment—

14 “(i) for any specific covered out-
15 patient drug, or specific class of covered
16 outpatient drug; or

17 “(ii) for any specific use of such a
18 drug for a specific indication unless such
19 exclusion is pursuant to section 1862(a)(1)
20 based on a finding by the Secretary that
21 such use is not safe or is not effective.

22 “(6) TREATMENT OF CERTAIN PREPAID ORGA-
23 NIZATIONS.—

24 “(A) GENERAL RULE COUNTING PREPAID
25 PLAN EXPENSES TOWARD THE PRESCRIPTION

1 DRUG DEDUCTIBLE.—Except as provided in
2 subparagraph (B), expenses incurred by (or on
3 behalf of) a medicare beneficiary for covered
4 outpatient drugs shall be counted (consistent
5 with subparagraph (C)) toward the prescription
6 drug deductible established under paragraph
7 (1) whether or not, at the time the expenses
8 were incurred, the beneficiary was enrolled in a
9 plan under section 1833(a)(1)(A), a
10 Medicare+Choice plan under part C, or under
11 section 1876.

12 “(B) TREATMENT OF DRUG BUY-OUT PLAN
13 EXPENSES.—In the case of a medicare bene-
14 ficiary enrolled in a month in a drug buy-out
15 plan (as defined in subparagraph (D))—

16 “(i) expenses incurred by the bene-
17 ficiary for covered outpatient drugs reim-
18 bursed under the plan shall not be counted
19 toward the prescription drug deductible,
20 but

21 “(ii) if the individual disenrolls from
22 the plan during the year, the beneficiary is
23 deemed to have incurred, for each month
24 of such enrollment, expenses for covered
25 outpatient drugs in an amount equal to the

1 actuarial value (with respect to such
2 month) of the deductible for covered out-
3 patient drugs (as computed by the Sec-
4 retary for purposes of section 1876(e)(1))
5 applicable on the average to individuals in
6 the United States.

7 “(C) TREATMENT OF EXPENSES FOR COV-
8 ERED OUTPATIENT DRUGS INCURRED WHILE
9 ENROLLED IN A PREPAID PLAN OTHER THAN A
10 DRUG BUY-OUT PLAN.—The Secretary may not
11 enter into a contract with a Medicare+Choice
12 organization under part C, an organization
13 under section 1876, or provide for payment
14 under section 1833(a)(1)(A) with respect to an
15 organization which provides reimbursement for
16 covered outpatient drugs, with respect to a plan
17 that is not a drug buy-out plan, unless the or-
18 ganization provides assurances, satisfactory to
19 the Secretary, that—

20 “(i) the organization will maintain
21 and make available, for its enrollees and in
22 coordination with the appropriate carriers
23 under this part, an accounting of expenses
24 incurred by (or on behalf of) enrollees

1 under the plan for covered outpatient
2 drugs; and

3 “(ii) the organization will take into
4 account, in any deductibles established
5 under the plan in a year with respect to
6 covered outpatient drugs under this part,
7 the amounts of expenses for covered out-
8 patient drugs incurred in the year by (or
9 on behalf of) the beneficiary and otherwise
10 counted toward the prescription drug de-
11 ductible in the year.

12 “(D) DRUG BUY-OUT PLAN DEFINED.—In
13 this paragraph, the term ‘drug buy-out plan’
14 means a plan under section 1833(a)(1)(A) or
15 offered by a Medicare+Choice organization
16 under part C, or an organization under section
17 1876 and with respect to which—

18 “(i) the amount of any deductible
19 under the plan with respect to covered out-
20 patient drugs under this title,
21 is less than 50 percent of—

22 “(ii) the prescription drug deductible
23 specified in paragraph (1)(C).

24 “(E) MEDICARE BENEFICIARY DEFINED.—
25 In this subsection, the term ‘Medicare bene-

1 ficiary' means, with respect to a month, an in-
2 dividual covered for benefits under this part for
3 the month.

4 “(F) TREATMENT OF PLAN CHARGES.—In
5 the case of covered outpatient drugs furnished
6 by a Medicare+Choice organization under part
7 C, an eligible organization under section
8 1876(b) or an organization described in section
9 1833(a)(1)(A) which does not impose charges
10 on covered outpatient drugs dispensed to its
11 members, for purposes of this subsection the
12 actual charges of the organization shall be the
13 organization's standard charges to members,
14 and other individuals, not entitled to benefits
15 with respect to such drugs.

16 “(7) PHYSICIAN GUIDE.—

17 “(A) IN GENERAL.—The Secretary shall
18 develop, and update annually, an information
19 guide for physicians concerning the comparative
20 average wholesale prices of at least 500 of the
21 most commonly prescribed covered outpatient
22 drugs. Such guide shall, to the extent prac-
23 ticable, group covered outpatient drugs (includ-
24 ing multiple source drugs) in a manner useful
25 to physicians by therapeutic category or with

1 respect to the conditions for which they are pre-
2 scribed. Such guide shall specify the average
3 wholesale prices on the basis of the amount of
4 the drug required for a typical daily therapeutic
5 regimen.

6 “(B) MAILING GUIDE.—The Secretary
7 shall provide for mailing, in January of each
8 year (beginning with 2001), a copy of the guide
9 developed and updated under subparagraph
10 (A)—

11 “(i) to each hospital with an agree-
12 ment in effect under section 1866;

13 “(ii) to each physician (as defined in
14 section 1861(r)(1)) who routinely provides
15 services under this part; and

16 “(iii) to Social Security offices, senior
17 citizen centers, and other appropriate
18 places.

19 “(8) REPORTS ON UTILIZATION AND EFFECTS
20 ON PRICES.—

21 “(A) COMPILATION OF INFORMATION.—
22 The Secretary shall compile information on—

23 “(i) manufacturers’ prices for covered
24 outpatient drugs, and on charges of phar-
25 macists for covered outpatient drugs, and

1 “(ii) the use of covered outpatient
2 drugs by individuals entitled to benefits
3 under this part.

4 The information compiled under clause (i) shall
5 include a comparison of the increases in prices
6 and charges for covered outpatient drugs dur-
7 ing each 6 month period (beginning with Janu-
8 ary 1999) with the semiannual average increase
9 in such prices and charges during the 5 years
10 beginning with 1993.

11 “(B) REPORTS.—The Secretary shall sub-
12 mit to the Committees on Ways and Means and
13 Commerce of the House of Representatives and
14 the Committee on Finance of the Senate a re-
15 port, in May and November of 2000 and 2001
16 and in May of each succeeding year, providing
17 the information compiled under subparagraph
18 (A). For each such report submitted after
19 2002, the report shall include an explanation of
20 the extent to which the increases in outlays for
21 covered outpatient drugs under this part are
22 due to the factors described in subparagraphs
23 (A)(i) and (A)(ii).

24 “(9) DEFINITIONS.—In this subsection:

25 “(A) MULTIPLE SOURCE DRUG.—

1 “(i) IN GENERAL.—The term ‘mul-
2 tiple source drug’ means, with respect to a
3 payment calculation period, a covered out-
4 patient drug for which there are 2 or more
5 drug products which—

6 “(I) are rated as therapeutically
7 equivalent (under the Food and Drug
8 Administration’s most recent publica-
9 tion of ‘Approved Drug Products with
10 Therapeutic Equivalence Evalua-
11 tions’);

12 “(II) except as provided in clause
13 (ii), are pharmaceutically equivalent
14 and bioequivalent, as defined in clause
15 (iii) and as determined by the Food
16 and Drug Administration; and

17 “(III) are sold or marketed dur-
18 ing the period.

19 “(ii) EXCEPTION.—Subclause (II) of
20 clause (i) shall not apply if the Food and
21 Drug Administration changes by regulation
22 (after an opportunity for public comment
23 of 90 days) the requirement that, for pur-
24 poses of the publication described in clause
25 (i)(I), in order for drug products to be

1 rated as therapeutically equivalent, they
2 must be pharmaceutically equivalent and
3 bioequivalent, as defined in clause (iii).

4 “(iii) DEFINITIONS.—For purposes of
5 this subparagraph:

6 “(I) PHARMACEUTICALLY EQUIV-
7 ALENT.—Drug products are pharma-
8 ceutically equivalent if the products
9 contain identical amounts of the same
10 active drug ingredient in the same
11 dosage form and meet compendial or
12 other applicable standards of strength,
13 quality, purity, and identity.

14 “(II) BIOEQUIVALENT.—Drugs
15 are bioequivalent if they do not
16 present a known or potential bio-
17 equivalence problem or, if they do
18 present such a problem, are shown to
19 meet an appropriate standard of bio-
20 equivalence.

21 “(III) SOLD OR MARKETED.—A
22 drug is considered to be sold or mar-
23 keted during a period if it is listed in
24 the publications referred to in clause
25 (i)(I), unless the Secretary determines

1 that such sale or marketing is not ac-
2 tually taking place.

3 “(B) RESTRICTIVE PRESCRIPTION.—A
4 drug has a ‘restrictive prescription’ only if—

5 “(i) in the case of a written prescrip-
6 tion, the prescription for the drug indi-
7 cates, in the handwriting of the physician
8 or other person prescribing the drug and
9 with an appropriate phrase (such as ‘brand
10 medically necessary’) recognized by the
11 Secretary, that the particular drug must be
12 dispensed; or

13 “(ii) in the case of a prescription
14 issued by telephone—

15 “(I) the physician or other per-
16 son prescribing the drug (through use
17 of such an appropriate phrase) states
18 that the particular drug must be dis-
19 pensed, and

20 “(II) the physician or other per-
21 son submits to the pharmacy involved,
22 within 30 days after the date of the
23 telephone prescription, a written con-
24 firmation which is in the handwriting
25 of the physician or other person pre-

1 scribing the drug and which indicates
2 with such appropriate phrase that the
3 particular drug was required to have
4 been dispensed.

5 “(C) PAYMENT CALCULATION PERIOD.—
6 The term ‘payment calculation period’ means
7 the 6-month period beginning with January of
8 each year and the 6-month period beginning
9 with July of each year.”.

10 (c) PARTICIPATING PHARMACIES; CIVIL MONEY
11 PENALTIES.—

12 (1) PARTICIPATING PHARMACIES.—Section
13 1842 of such Act (42 U.S.C. 1395t) is amended—

14 (A) in subsection (h)(1), by inserting be-
15 fore the period at the end of the second sen-
16 tence the following: “, except that, with respect
17 to a supplier of covered outpatient drugs, the
18 term ‘participating supplier’ means a partici-
19 pating pharmacy (as defined in subsection
20 (o)(1))”;

21 (B) in subsection (h)(4), by adding at the
22 end the following: “In publishing directories
23 under this paragraph, the Secretary shall pro-
24 vide for separate directories (wherever appro-
25 priate) for participating pharmacies.”; and

1 (C) by inserting after subsection (t) the
2 following new subsection:

3 “(u)(1) For purposes of this section, the term ‘par-
4 ticipating pharmacy’ means, with respect to covered out-
5 patient drugs dispensed on or after January 1, 2001, an
6 entity which is authorized under a State law to dispense
7 covered outpatient drugs and which has entered into an
8 agreement with the Secretary, providing at least the fol-
9 lowing:

10 “(A) The entity agrees to accept payment under
11 this part on an assignment-related basis for all cov-
12 ered outpatient drugs dispensed to an individual en-
13 titled to benefits under this part (in this subsection
14 referred to as a ‘Medicare beneficiary’) during a
15 year after—

16 “(i) the Secretary has notified the entity,
17 through the electronic system described in para-
18 graph (4); or

19 “(ii) in the absence of such a system, the
20 entity is otherwise notified that the Secretary
21 has determined,
22 that the individual has met the prescription drug de-
23 ductible with respect to such drugs under section
24 1834(e)(1) for the year.

25 “(B) The entity agrees—

1 “(i) not to refuse to dispense covered out-
2 patient drugs stocked by the entity to any medi-
3 care beneficiary; and

4 “(ii) not to charge Medicare beneficiaries
5 (regardless of whether or not the beneficiaries
6 are enrolled under a prepaid health plan, a
7 Medicare+Choice organization under part C, or
8 with eligible organization under section 1876)
9 more for such drugs than the amount it charges
10 to the general public (as determined by the Sec-
11 retary in regulations).

12 “(C) The entity agrees to keep patient records
13 (including records on expenses) for all covered out-
14 patient drugs dispensed to all medicare beneficiaries.

15 “(D) The entity agrees to submit information
16 (in a manner specified by the Secretary to be nec-
17 essary to administer this title) on all purchases of
18 covered outpatient drugs dispensed to medicare
19 beneficiaries.

20 “(E) The entity agrees—

21 “(i) to offer to counsel, or to offer to pro-
22 vide information (consistent with State law re-
23 specting the provision of such information) to,
24 each Medicare beneficiary on the appropriate
25 use of a drug to be dispensed and whether there

are potential interactions between the drug and other drugs dispensed to the beneficiary; and

“(ii) to advise the beneficiary on the availability (consistent with State laws respecting substitution of drugs) of therapeutically equivalent covered outpatient drugs.

“(F) The entity agrees to provide the information requested by the Secretary in surveys under section 1834(e)(3)(C)(ii).

Nothing in this paragraph shall be construed as requiring a pharmacy operated by a Medicare+Choice organization under part C, an eligible organization (described in section 1876(b)) or an organization described in section 1833(a)(1)(A) for the exclusive benefit of its members to dispense covered outpatient drugs to individuals who are not members of the organization.

“(2) The Secretary shall provide to each participating pharmacy—

“(A) a distinctive emblem (suitable for display to the public) indicating that the pharmacy is a participating pharmacy; and

“(B) upon request, such electronic equipment and technical assistance (other than the costs of obtaining, maintaining, or expanding telephone service) as the Secretary determines may be necessary for

1 the pharmacy to submit claims using the electronic
2 system established under paragraph (4).

3 “(3) The Secretary shall provide for periodic audits
4 of participating pharmacies to assure—

5 “(A) compliance with the requirements for par-
6 ticipation under this title; and

7 “(B) the accuracy of information submitted by
8 the pharmacies under this title.

9 “(4) The Secretary shall establish, by not later than
10 January 1, 2001, a point-of-sale electronic system for use
11 by carriers and participating pharmacies in the submission
12 of information respecting covered outpatient drugs dis-
13 pensed to medicare beneficiaries under this part.

14 “(5) Notwithstanding subsection (b)(3)(B), payment
15 for covered outpatient drugs may be made on the basis
16 of an assignment described in clause (ii) of that subsection
17 only to a participating pharmacy.”.

18 (2) CIVIL MONEY PENALTIES FOR VIOLATION
19 OF PARTICIPATION AGREEMENT, FOR EXCESSIVE
20 CHARGES FOR NONPARTICIPATING PHARMACIES AND
21 FOR FAILURE TO PROVIDE SURVEY INFORMATION.—
22 Section 1128A(a) of such Act (42 U.S.C. 1320a-
23 7a(a)) is amended—

1 (A) in paragraph (2)(C), by inserting “or
2 to be a participating pharmacy under section
3 1842(u)” after “1842(h)(1)”;

4 (B) by striking “, or” at the end of para-
5 graph (6);

6 (C) by adding “or” at the end of para-
7 graph (7); and

8 (D) by inserting after paragraph (7) the
9 following new paragraph:

10 “(8) in the case of a participating or non-
11 participating pharmacy (as defined for purposes of
12 part B of title XVIII)—

13 “(A) presents or causes to be presented to
14 any person a request for payment for covered
15 outpatient drugs dispensed to an individual en-
16 titled to benefits under part B of title XVIII
17 and for which the amount charged by the phar-
18 macy is greater than the amount the pharmacy
19 charges the general public (as determined by
20 the Secretary in regulations), or

21 “(B) fails to provide the information re-
22 quested by the Secretary in a survey under sec-
23 tion 1834(e)(3)(C)(ii);”.

1 (d) LIMITATION ON LENGTH OF PRESCRIPTION.—
2 Section 1862(c) of such Act (42 U.S.C. 1395y(c)) is
3 amended—

4 (1) by redesignating subparagraphs (A) through
5 (D) of paragraph (1) as clauses (i) through (iv) re-
6 spectively;

7 (2) in paragraph (2)(A), by striking “paragraph
8 (1)” and inserting “subparagraph (A)”;

9 (3) by redesignating subparagraphs (A) and
10 (B) of paragraph (2) as clauses (i) and (ii) respec-
11 tively;

12 (4) by redesignating paragraphs (1) and (2) as
13 subparagraphs (A) and (B) respectively;

14 (5) by inserting “(1)” after “(c)”; and

15 (6) by adding at the end the following new
16 paragraph:

17 “(2) No payment may be made under part B for any
18 expense incurred for a covered outpatient drug if the drug
19 is dispensed in a quantity exceeding a supply of 30 days
20 or such longer period of time (not to exceed 90 days, ex-
21 cept in exceptional circumstances) as the Secretary may
22 authorize.”.

23 (e) USE OF CARRIERS, FISCAL INTERMEDIARIES,
24 AND OTHER ENTITIES IN ADMINISTRATION.—

(1) AUTHORIZING USE OF OTHER ENTITIES IN ELECTRONIC CLAIMS SYSTEM.—Section 1842(f) of such Act (42 U.S.C. 1395u(f)) is amended—

(A) by striking “and” at the end of paragraph (1);

(B) by striking the period at the end of paragraph (2) and inserting “; and”; and

(C) by adding at the end the following new paragraph:

“(3) with respect to implementation and operation (and related functions) of the electronic system established under subsection (u)(4), a voluntary association, corporation, partnership, or other non-governmental organization, which the Secretary determines to be qualified to conduct such activities.”.

(2) ADDITIONAL FUNCTIONS OF CARRIERS.—Section 1842(b)(3) of such Act (42 U.S.C. 1395u(b)(3)) is amended—

(A) by striking “and” at the end of subparagraph (I);

(B) by redesignating subparagraph (L) as subparagraph (J); and

(C) by inserting after subparagraph (J) (as so redesignated) the following new subparagraphs:

1 “(K) if it makes determinations or payments
2 with respect to covered outpatient drugs, will—

3 “(i) receive information transmitted under
4 the electronic system established under sub-
5 section (u)(4), and

6 “(ii) respond to requests by participating
7 pharmacies (and individuals entitled to benefits
8 under this part) as to whether or not such an
9 individual has met the prescription drug de-
10 ductible established under section
11 1834(e)(1)(A) for a year; and

12 “(L) will enter into such contracts with organi-
13 zations described in subsection (f)(3) as the Sec-
14 retary determines may be necessary to implement
15 and operate (and for related functions with respect
16 to) the electronic system established under sub-
17 section (u)(4) for covered outpatient drugs under
18 this part.”.

19 (3) SPECIAL CONTRACT PROVISIONS FOR ELEC-
20 TRONIC CLAIMS SYSTEM.—

21 (A) PAYMENT ON OTHER THAN A COST
22 BASIS.—Section 1842(c)(1) of such Act (42
23 U.S.C. 1395u(c)(1)) is amended—

24 (i) by inserting “(A)” after “(c)(1)”;

1 (ii) in the first sentence, by inserting
2 “, except as provided in subparagraph
3 (B),” after “under this part, and”; and
4 (iii) by adding at the end the fol-
5 lowing new subparagraph:

6 “(B) To the extent that a contract under this section
7 provides for implementation and operation (and related
8 functions) of the electronic system established under sub-
9 section (u)(4) for covered outpatient drugs, the Secretary
10 may provide for payment for such activities based on any
11 method of payment determined by the Secretary to be ap-
12 propriate.”.

13 (B) APPLICATION OF DIFFERENT PER-
14 FORMANCE STANDARDS.—The Secretary of
15 Health and Human Services, before entering
16 into contracts under section 1842 of the Social
17 Security Act with respect to the implementation
18 and operation (and related functions) of the
19 electronic system for covered outpatient drugs,
20 shall establish standards with respect to per-
21 formance with respect to such activities. The
22 provisions of section 1153(e)(2) and paragraphs
23 (1) and (2) of section 1153(h) of such Act shall
24 apply to such activities in the same manner as
25 they apply to contracts with peer review organi-

1 zations, instead of the requirements of the sec-
2 ond and third sentences of section
3 1842(b)(2)(A) of such Act.

4 (C) USE OF REGIONAL CARRIERS.—Section
5 1842(b)(2)(A) of such Act (42 U.S.C.
6 1395u(b)(2)(A)) is amended by adding at the
7 end the following new sentence: “With respect
8 to activities relating to implementation and op-
9 eration (and related functions) of the electronic
10 system established under subsection (u)(4), the
11 Secretary may enter into contracts with carriers
12 under this section to perform such activities on
13 a regional basis.”.

14 (4) DELAY IN APPLICATION OF COORDINATED
15 BENEFITS WITH MEDIGAP.—The provisions of sub-
16 paragraph (B) of section 1842(h)(3) of the Social
17 Security Act shall not apply to covered outpatient
18 drugs (other than drugs described in section
19 1861(s)(2)(J) of such Act as of the date of the en-
20 actment of this Act) dispensed before January 1,
21 2002.

22 (5) BATCH PROMPT PROCESSING OF CLAIMS.—
23 Section 1842(e) of such Act (42 U.S.C. 1395u(e)),
24 is amended—

1 (A) by redesignating paragraph (6) as
2 paragraph (7);

3 (B) in paragraphs (2)(A) and (3)(A), by
4 striking “Each” and inserting “Except as pro-
5 vided in paragraph (6), each”; and

6 (C) by inserting after paragraph (5) the
7 following new paragraph:

8 “(6)(A) Each contract under this section which pro-
9 vides for the disbursement of funds, as described in sub-
10 section (a)(1)(B), with respect to claims for payment for
11 covered outpatient drugs shall provide for a payment cycle
12 under which each carrier will, on a monthly basis, make
13 a payment with respect to all claims which were received
14 and approved for payment in the period since the most
15 recent date on which such a payment was made with re-
16 spect to the participating pharmacy or individual submit-
17 ting the claim.

18 “(B) If payment is not issued, mailed, or otherwise
19 transmitted within 5 days of when such a payment is re-
20 quired to be made under subparagraph (A), interest shall
21 be paid at the rate used for purposes of section 3902(a)
22 of title 31, United States Code (relating to interest pen-
23 alties for failure to make prompt payments) for the period
24 beginning on the day after such 5-day period and ending
25 on the date on which payment is made.”.

1 (f) MODIFICATION OF HMO/CMP CONTRACTS.—

2 (1) SEPARATE ACTUARIAL DETERMINATION
3 FOR COVERED OUTPATIENT DRUG BENEFIT.—Section
4 tion 1876(e)(1) of such Act (42 U.S.C.
5 1395mm(e)(1)) is amended by adding at the end
6 thereof the following new sentence: “The preceding
7 sentence shall be applied separately with respect to
8 covered outpatient drugs.”.

9 (2) ADDITIONAL OPTIONAL BENEFITS.—Section
10 1876(g)(3)(A) of such Act (42 U.S.C.
11 1395mm(g)(3)(A)) is amended by striking “rate”
12 and inserting “rates”.

13 (g) CONFORMING AMENDMENTS.—

14 (1) The first sentence of section 1866(a)(2)(A)
15 (42 U.S.C. 1395cc(a)(2)(A)) is amended—

16 (A) by inserting “1834(e),” after
17 “1833(b),”; and

18 (B) by inserting “and in the case of cov-
19 ered outpatient drugs, applicable coinsurance
20 percent (specified in section 1834(e)(2)(C)) of
21 the lesser of the actual charges for the drugs or
22 the payment limit (established under section
23 1834(d)(3))” after “established by the Sec-
24 retary)”.

1 (2) Section 1903(i)(5) (42 U.S.C. 1396b(i)(5))
2 is amended by striking “section 1862(c)” and insert-
3 ing “section 1862(c)(1)”.

4 (h) PRESCRIPTION DRUG PAYMENT REVIEW COM-
5 MISSION.—Part B is amended by inserting after section
6 1844 the following new section:

7 “PRESCRIPTION DRUG PAYMENT REVIEW COMMISSION

8 “SEC. 1845. (a)(1) The Director of the Congressional
9 Office of Technology Assessment (in this section referred
10 to as the ‘Director’ and the ‘Office’, respectively) shall
11 provide for the appointment of a Prescription Drug Pay-
12 ment Review Commission (in this section referred to as
13 the ‘Commission’), to be composed of individuals with ex-
14 pertise in the provision and financing of covered out-
15 patient drugs appointed by the Director (without regard
16 to the provisions of title 5, United States Code, governing
17 appointments in the competitive service).

18 “(2) The Commission shall consist of 11 individuals.
19 Members of the Commission shall first be appointed by
20 no later than January 1, 2000, for a term of 3 years, ex-
21 cept that the Director may provide initially for such short-
22 er terms as will ensure that (on a continuing basis) the
23 terms of no more than 4 members expire in any one year.

24 “(3) The membership of the Commission shall in-
25 clude recognized experts in the fields of health care eco-
26 nomics, medicine, pharmacology, pharmacy, and prescrip-

1 tion drug reimbursement, as well as at least one individual
2 who is a medicare beneficiary.

3 “(b)(1) The Commission shall submit to Congress an
4 annual report no later than May 1 of each year, beginning
5 with 2001, concerning methods of determining payment
6 for covered outpatient drugs under this part.

7 “(2) Such report, in 2002 and thereafter, shall in-
8 clude, with respect to the previous year, information on—

9 “(A) increases in manufacturers’ prices for cov-
10 ered outpatient drugs and in charges of pharmacists
11 for covered outpatient drugs,

12 “(B) the level of utilization of covered out-
13 patient drugs by medicare beneficiaries, and

14 “(C) administrative costs relating to covered
15 outpatient drugs.

16 “(c) The following provisions of section 1805 shall
17 apply to the Commission in the same manner as they
18 apply to the Medicare Payment Advisory Commission:

19 “(1) Subsection (c)(4) (relating to compensa-
20 tion of members).

21 “(2) Subsection (d) (relating to staffing and ad-
22 ministration).

23 “(3) Subsection (e) (relating to powers of the
24 Commission generally).

1 “(4) Subsection (f)(1) (relating to requests for
2 appropriations).

3 “(d) There are authorized to be appropriated such
4 sums as may be necessary to carry out the provisions of
5 this section. Such sums shall be payable from the Federal
6 Supplementary Medical Insurance Trust Fund.”.

7 (i) DEVELOPMENT OF STANDARD MEDICARE CLAIMS
8 FORM.—

9 (1) The Secretary shall develop, in consultation
10 with representatives of pharmacies and other inter-
11 ested individuals, a standard claims form (and a
12 standard electronic claims format) to be used in re-
13 quests for payment for covered outpatient drugs
14 under the medicare program and other third-party
15 payors.

16 (2) Not later than October 1, 2000, the Sec-
17 retary shall distribute official sample copies of the
18 format developed under paragraph (1) to pharmacies
19 and other interested parties and by not later than
20 October 1, 2000, shall distribute official sample cop-
21 ies of the form developed under paragraph (1) to
22 pharmacies and other interested parties.

23 (j) EFFECTIVE DATES.—

24 (1) IN GENERAL.—Except as otherwise pro-
25 vided in this subsection, the amendments made by



1 this section shall apply to items dispensed on or
2 after January 1, 2001.

3 (2) CARRIERS.—The amendments made by sub-
4 section (e) shall take effect on the date of the enact-
5 ment of this Act; except that the amendments made
6 by subsection (e)(5) shall take effect on January 1,
7 2002, but shall not be construed as requiring pay-
8 ment before February 1, 2002.

9 (3) HMO/CMP ENROLLMENTS.—The amend-
10 ment made by subsection (f) shall apply to enroll-
11 ments effected on or after January 1, 2001.

○